K052587

DEC 2 7 2005

510(k) SUMMARY

J. Morita USA. Inc.'s
3D Accu-I-tomo XYZ Slice View Tomograph
MCT-1 EX F

1. **Submitter Name and Address with Phone/Fax :**

Registration No. 2081055
Initial Distributor:
J. Morita USA, Inc.
9 Mason
Irvine, CA 92618
USA
Telephone: 949-581-9600
Facsimile: 949-581-9688

2. **Contact Person**

Keith A. Barritt
Fish & Richardson P.C.
1425 K Street, N.W.
Suite 1100
Washington, DC 20005
Phone: (202) 783-5070
Facsimile: (202) 783-2331

3. **Date summary prepared:** August 31, 2005

4. **Device Name:**
Trade or Proprietary Name: 3D Accu-I-tomo XYZ Slice View Tomograph
Model: MCT-1 EX F

Common Name: Cone beam x-ray CT

Classification Name: Computed tomography x-ray system
(21CFR 892.1750)

Product Code : 90JAK

5. **Substantial Equivalency is claimed against the following device:**
3D Accu-I-tomo XYZ Slice View Tomograph MCT-1 EX From
J. MORITA MFG.CORP. 510k # K030450

6. Description of the device:

The MCT-1 EX F is an X-ray CT using the limited cone beam. MCT-1 EX F makes diagnosis be possible due to its high resolution three dimensional images for small regions within a limited area of the extremely complex morphology of the hard tissue of the head and neck region

High resolution images are obtained in the same short period as that of the Panoramic Radiology. Low X-ray radiation dosage is realized and the overall system structure is assembled to be compact unit.

The J.MORITA. MFG. CORP. has manufactured the MCT-1EX as the original model of such kind of X-ray scanner, and modify the device for MCT-1 EX F by replacing the image receptor , XII for FPD (Flat Panel Detector).

7. Intended Use

The MCT-1 EX F is intended to be used for three dimensional X-ray Computed Tomography of the head and neck by limited cone shaped x-ray beam projected on to an FPD to be operated and used by doctors, dentists, properly licensed professionals and other legally qualified professionals.

8. Safety and effectiveness of the device

As the MCT-1 EX F is modified from our legally marketed device, MCT- 1 EX (K#030450) by replacing image receptor from XII to FPD with remaining all the other parts be common, so that the MCT-1 EX F is substantially equivalent to MCT-1EX as is shown in the comparison summary table below because they have similar general intended uses, technological characteristics and operating principles.

Any differences in the technological characteristics do not raise any new issues of safety or effectiveness.

	This new submission	Predicate	Difference
Name of the model	MCT-1 EX F	MCT-1EX	Different
Manufacturer	J.MORITA MFG. CORP.	J.MORITA MFG. CORP.	Identical
Construction	Rotating arm and base	Rotating arm and base	Same
Image Receptor	Flat Panel Detector	X-ray image intensifier	Different
Chin Rest	Equipped	Equipped NOTE-1	Identical
Performance spec.	Computed tomography	Computed tomography	Identical
Mechanical	MCT mechanism	MCT mechanism	Same
Electrical	MCT electric circuit	MCT electric circuit	Same
Software	MCT software	MCT software	Identical
Testing	VDE NOTE-2	VDE NOTE-2	Same

NOTE-1 The original submission does not include Chin rest , but this is included in MCT-1EX through our in-house revision procedure named "510(K) memo " documentation as shown at Attachment 11 in this submission.

NOTE-2 The notified body of VDE has tested and certified for CE marking with CB report on MCT-1 EX F which is to be accessed

Substantial Equivalent comparison summary table
MCT-1 EX F to MCT-1EX

FDA file reference number	510k number of MCT-1EX K030450
TECHNOLOGICAL CHARACTERISTICS	**Comparison result**
Indication for use	Identical
Target population	Identical
Design	Similar
Materials	Similar
Performance	Identical
Sterility	Similar
Biocompatibility	Similar
Mechanical safety	Similar
Chemical safety	Similar
Anatomical sites	Identical
Human factors	Identical
Energy used and/or delivered	Identical
Compatibility with environment and other devices	Identical
Where used	Identical
Standards met	Similar
Electrical safety	Similar
Thermal safety	Similar
Radiation safety	Similar

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 7 2005

J. Morita USA, Inc.
c/o Mr. Keith A. Barritt
Fish & Richardson P.C.
1425 K Street, N.W., Suite 1100
11th Floor
WASHINGTON DC 200005

Re: K052587
Trade/Device Name: 3D Accu-I-tomo XYZ Slice View Tomograph Model MCT-1 EXF
Regulation Number: 21 CFR §892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: September 19, 2005
Received: October 11, 2005

Dear Mr. Barritt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052587

Device Name: 3D Accu-I-tomo XYZ Slice View Tomograph Model MCT-1 EXF

Indications For Use:

The Model MCT-1 EXF is an x-ray imaging device that acquires a 360 degree rotational sequence of the head and neck areas, including the ENT and dento-maxillofacial areas, for use in diagnostic support. The device accomplishes this task by reconstructing a three-dimensional matrix of the examined volume and producing two-dimensional views of this volume, displaying both two- and three-dimensional images. The device is operated and used by physicians, dentists, and x-ray technologists.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Lehrman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052587